DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
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Telephone: 425-486-8788
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June 7, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-48

Michael J. Guest, General Manager
Osmonics
7848 South 202nd Street
Kent, Washington 98032-1345

WARNING LETTER

Dear Mr. Guest:

We are writing to you because during an inspection from March 14–30, 2000, the Food and Drug Administration (FDA) became aware of information that revealed a serious regulatory problem involving the Millenium Portable Reverse Osmosis (RO) System which is manufactured and marketed by your firm.

The inspection found that this device is adulterated within the meaning of Section 501(h) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

1. Failure to establish procedures for quality audits and to conduct such audits to assure that the quality system is in compliance with the established quality system requirements.

2. Failure to establish and implement management review of the quality system.

3. Failure to establish and implement design control procedures. For example, design controls were not implemented for the following: the Millenium Reverse Osmosis device; redesign of pump endplate assemblies; and redesign of a caster mounting plate.

4. Procedures for implementing corrective and preventive action are incomplete. Corrective and preventive action activities have not been documented. Quality data has not been analyzed as part of the corrective and preventive action.

5. Failure to train personnel to adequately perform their assigned responsibilities and to document such training. For example, the root causes of seven complaints (leaky manifold, solenoid valves installed incorrectly, and poor welds) were attributable to employee training failures.

6. Failure to follow procedures for acceptance or rejection of incoming products. For example, 31 of 36 shipments of cabinet assemblies, motor brackets, and cable assembly kits were accepted without sampling.

7. Failure to establish and maintain procedures to ensure that all purchased products conform to specified requirements. For example, a contract manufacturer has modified a component and the manufacturing process for another different component, without approval by Osmonics.

8. Failure to establish and maintain procedures to control all documents. For example, four test documents for reverse osmosis systems and solution distribution systems have not been approved.

Additionally, the inspection revealed that the device is misbranded within the meaning of Section 502(t)(2) of the Act, in that your firm failed to submit information to FDA as required by the Medical Device Reporting (MDR) regulation as specified in 21 CFR Part 803. Specifically, your firm failed to report two complaints:

1. Complaint 9906073 dated June 24, 1999, from [redacted] concerns a wheel that fell off a S750 RO model. The hospital reported that the nurse who stabilized the equipment until the wheel was reattached by another employee had been involved with a previous identical incident in which her shoulder was injured.

   MDR 3019131-2000-00004 was filed by your firm on April 12, 2000, as an adverse event, type "other." The report should have been identified as a "malfunction."

2. Complaint 9906031 dated June 11, 1999, reported by [redacted] concerned a cart from a 700 series reverse osmosis system, model 14536, and identified four serial numbers. The complainant stated that the castors are too small and the legs are bending on this model. As a result of this complaint, your firm implemented an engineering evaluation and redesign. MDR malfunction reports should have been filed for the four units identified in the complaint.

   Four MDRs, 3019131-2000-00002 and 7/9 were filed by your firm on April 20, 2000, as product problems, type "Other." They should have been "malfunctions."

Additionally, your firm's document, *MDR Reporting Procedure*, *Rev. E*, has statements which are inconsistent with the new MDR regulation, effective July 31, 1996. Specifically:

Page 3 has references to definitions in 21 CFR Part 803 that are from the old regulation that was effective December 13, 1984. The definitions should be revised to be consistent with the new regulation.

> Para. 5.7 – "Reportable events" are now defined in 21 CFR 803.20(b) and not 803.24(a). The current reference to events that are reportable even if due to user error may be found in 21 CFR 803.3(d).
> Para. 6.4 – The exemption criteria of 21 CFR 803.24(d)(3) no longer applies.

Page 4 contains the requirements for five (5) day telephone and 15 day written reports which were mandatory under the 1984 regulation. The current regulation requires 30 day written reports for reportable events, unless there is a significant risk to public health which requires a five (5) day written report. Although permission to send via facsimile is still an option, the correct phone number to call for permission to fax is now 301-827-0360.

Page 5 includes references to the 1984 MDR requirements rather than those in the current regulation:

> Para. 7.5.1 – identifies the old address for written reports instead of the current address which is, P.O. Box 3002, Rockville, MD 20847-3002.
> Para. 7.5.2 – incorrectly states malfunctions are due in 15 days instead of the correct 30 days.
> Para. 7.6 – references frequency and severity statements that are no longer required.

Page 6 – Attachment A should be updated in accordance with the Medwatch form 3500A.

Pages 7 and 8 – Attachments B and C should reflect the use of the Medwatch form 3500A and submission of supplemental reports, not the 15 day follow-up malfunction reports under the 1984 regulation.

Page 9 – The flow chart must be updated in accordance with the above comments.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal

Agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. We have received a letter dated April 13, 2000, from Mr. Patrick Lynch, RA/QA Manager, addressing the inspectional findings. In his correspondence, Mr. Lynch had specified deadlines for correcting the deficiencies. Please let this office know in writing within fifteen (15) working days from the date you received this letter the progress you are taking to correct the problems including revision of your *MDR Reporting Procedure, Rev. E.* If you need more time, let us know why and when you expect to complete your corrections. Please direct your response to Thomas S. Piekarski, Compliance Officer, at the above address.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of reporting corrections and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 800-638-2041 or through the Internet at www.fda.gov.

Sincerely yours,

Charles M. Breen
District Director

Encl.:
21 CFR Part 803

cc w/copy of FDA-483:
D. Dean Spatz
Chief Executive Officer
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